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Newark / Philadelphia

May 28, 2024

VIA ECF AND ELECTRONIC MAIL

Hon. Douglas E. Arpert, U.S.M.J. (Ret.)
Three Gateway Center
100 Mulberry Street
15th Floor
Newark, New Jersey 07102

**Re: *U.S. ex rel. Silbersher v. Janssen Biotech Inc.*
Civil Action No. 19-12107(MEF)(CLW)**

Dear Judge Arpert:

On April 26, 2024, Defendants moved to quash the deposition notice of Pearl Pugh based on Defendants' mistaken application of the apex doctrine (ECF No. 341). Relator filed his opposition on May 3, 2024 (ECF No. 344). With Your Honor's permission, Relator submits this letter providing Your Honor with excerpts from the depositions of Defendants' former employees, Eric Harris (**Exhibit A**) and Victoria Vakiener (**Exhibit B**), as their testimony relates to that motion.

As we explained in our opposition to Defendants' motion, the apex deposition doctrine does not apply to Ms. Pugh. Additionally, the recent depositions of Mr. Harris and Ms. Vakiener confirm that Ms. Pugh has unique and personal knowledge of important issues in this case.

On May 8, 2024, Relator took the deposition of Eric Harris. Mr. Harris was Johnson & Johnson's Senior Oncology Analytics and Forecasting analyst primarily in charge of creating Defendants' Long Range Forecast Projections for Zytiga from 2013 to 2014. (Ex. A, at 22 [describing responsibilities without specifying dates and exact title])

On May 17, 2024, Relator took the deposition of Victoria Vakiener, who was the Director of Marketing for Zytiga between 2013 to 2014, and Vice President of Oncology Marketing from 2014 to approximately 2020. (Ex. B, at 36 [without specifying dates])

As explained in Relator's Motion for *In Camera* Review of Documents Not Subject to Privilege Pursuant to the Crime-Fraud Exception, the long-range financial planning models play an important role in Relator's proof. (ECF No. 346, at 17-18 & Exhibits 22-24 of the accompanying Declaration of Bruce D. Greenberg, ECF No. 345-1). In particular, the assumptions used in the long-range financial forecasts demonstrate that Defendants knew that



Hon. Douglas E. Arpert, U.S.M.J. (Ret.)

May 28, 2024

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that the '438 Patent, which Relator alleges was fraudulently obtained, would be invalidated by the Patent Office or the courts and not remain in force for its full patent term.

Mr. Harris testified that he received the loss of exclusivity ("LOE") assumptions for generic entry challenging Zytiga from Defendants "marketing" department, likely to have been Ms. Victoria Vakiener during the time that Mr. Harris was in charge of Long Range Forecast Projections from 2013-14. (Ex. A, at 92). The Director of Marketing conveyed to him the patent expiration and loss of exclusivity assumptions he should use in modeling Zytiga's projected revenue and market share over a [REDACTED] time horizon.

Ms. Vakiener testified that [REDACTED]
[REDACTED] she provided the data and financial modeling analysts such as Mr. Harris with those critical patent expiration and LOE assumptions [REDACTED]
[REDACTED] (Ex. B, at 83-86) Ms. Vakiener confirmed that Ms. Pugh took over responsibility for this important function in 2014, and that Ms. Pugh would have the most direct knowledge of these critical assumptions from 2014 onward to the end of the relevant time period. (*Id.*, at 93

[REDACTED]; *see also id.* at 208-09)

Based on the foregoing, Your Honor should deny Defendants' motion (ECF No. 341).

Respectfully,

/s/ Bruce D. Greenberg

Bruce D. Greenberg

BDG:emp

cc: All Counsel of Record (via ECF and email)

EXHIBIT A

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UNITED STATES DISTRICT COURT

for the

DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA)

ex rel. SILBERSHER,)

Plaintiff,)

vs.) No. 19-12107(MEF)(ESK)

JANSSEN BIOTECH, INC., et al.,)

Defendants.)

_____)

VIDEO DEPOSITION OF ERIC HARRIS

MAY 8, 2024

Reported by: Rosalie A. Kramm, CSR No. 5469, RPR, CRR

1 So I would have put out a weekly forecast for 08:55:09
2 Zytiga that was updated throughout the year, and then run 08:55:12
3 a lot of the data analytics to check actuals against that 08:55:17
4 forecast. 08:55:21

5 So it is a very different type of forecasting. 08:55:23

6 Q. And is there other types of forecasting you 08:55:27
7 were doing besides the forecasting for the current year; 08:55:29
8 for example, were there longer-term forecasts you did for 08:55:34
9 Zytiga? 08:55:39

10 A. Yes, once a year there was a long-range 08:55:39
11 financial plan, often referred to as LRFP, and I worked 08:55:44
12 on the long-range financial plan as well. 08:55:48

13 Q. Any other types of forecasts that you worked on 08:55:52
14 for Zytiga? 08:55:57

15 A. None that I recall. 08:56:02

16 Q. In your LinkedIn profile, you've described this 08:56:05
17 position as -- or you've described your responsibilities 08:56:09
18 in the position as "forecasted future potential and 08:56:12
19 tracked actual performance of products in Janssen 08:56:16
20 Biotech's oncology portfolio"; is that right? 08:56:19

21 A. That's correct. 08:56:22

22 Q. Is that an accurate description of your 08:56:23
23 responsibilities? 08:56:25

24 A. Yes. 08:56:29

25 Q. Were there any drugs, other than Zytiga, that 08:56:31

1 Do you see that? 10:50:49

2 A. I do. 10:50:49

3 Q. And if you look halfway down the page, there is 10:50:51

4 a column labeled "LOE." 10:50:53

5 A. I see that. 10:50:56

6 Q. That stands for loss of exclusivity? 10:50:57

7 A. It does. 10:51:00

8 [REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

[REDACTED] [REDACTED]

15 [REDACTED] [REDACTED] 10:51:24

16 Q. Who was responsible for preparing this slide? 10:51:26

17 A. Me, it looks like. 10:51:32

18 Q. Where did you get the LOE assumptions? 10:51:35

19 A. Probably from marketing. 10:51:45

20 Q. Who, specifically? 10:51:48

21 A. More than likely it would have been Vicki 10:51:53

22 Vakiener, but I don't remember exactly. 10:51:55

23 Q. Would Ms. Vakiener be the person most likely to 10:51:59

24 know the answer to that question about where these LOE 10:52:02

25 projections came from? 10:52:05

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1 concludes today's deposition. The time off the record is 16:16:50

2 4:16 p.m. 16:16:52

3 (Recess was taken at 4:16 p.m.) 16:16:54

4 (Read/sign was not requested.)

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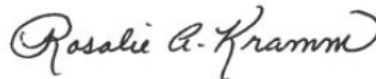
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REPORTER'S CERTIFICATE

I, Rosalie A. Kramm, Certified Shorthand Reporter for the State of California, do hereby certify:

That the witness named in the foregoing deposition was by me duly sworn; that the deposition was then taken before me at the time and place herein set forth; that the testimony and proceedings were reported stenographically by me and were transcribed through computerized transcription by me; that the foregoing is a true record of the testimony and proceedings taken at that time; and that I am not interested in the event of the action.

Witness my hand dated May 14, 2024.



ROSALIE A. KRAMM

CSR 5469, RPR, CRR

EXHIBIT B

HIGHLY CONFIDENTIAL

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

- - - - -x
 :
 UNITED STATES OF AMERICA, :
 STATE OF CALIFORNIA, :
 COLORADO, CONNECTICUT, :
 DELAWARE, FLORIDA, GEORGIA, :
 HAWAII, ILLINOIS, INDIANA, :
 IOWA, LOUISIANA, MICHIGAN, :
 MINNESOTA, MONTANA, NEVADA, :
 NEW JERSEY, NEW MEXICO, NEW :
 YORK, NORTH CAROLINA, :
 OKLAHOMA, RHODE ISLAND, : Civil Action
 TENNESSEE, TEXAS, VERMONT, : No.
 AND WASHINGTON; THE : 19-12107(MEF)(ESK)
 COMMONWEALTHS OF :
 MASSACHUSETTS AND VIRGINIA; :
 AND THE DISTRICT OF COLUMBIA, :
 Ex rel. ZACHARY SILBESHER, :
 Plaintiffs, :
 vs. :
 JANSSEN BIOTECH, INC., :
 JANSSEN ONCOLOGY, INC., :
 JANSSEN RESEARCH & :
 DEVELOPMENT, LLC, and JOHNSON :
 & JOHNSON, :
 Defendants. :

- - - - -x
 HIGHLY CONFIDENTIAL VIDEOTAPED DEPOSITION
 OF VICTORIA VAKIENER, a witness called by counsel
 for the Plaintiff Relator Zachary Silbersher, taken
 pursuant to the Federal Rules of Civil Procedure,
 before Jane M. Werner, Registered Merit Reporter and
 Notary Public in and for the Commonwealth of
 Massachusetts, at the Offices of Sidley Austin LLP,
 60 State Street, Boston, Massachusetts, on Friday,
 May 17, 2024, commencing at 9:38 a.m.

HIGHLY CONFIDENTIAL

PRESENT:

HERRERA KENNEDY LLP

BY: NICOMEDES SY HERRERA, ESQ.

BRET HEMBD, ESQ. (Via Zoom)

1300 Clay Street, Suite 600, Oakland, CA
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Silbersher.

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VIA ZOOM

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VIA ZOOM

MORGAN & MORGAN, PA

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202.736.8176

Also Present: Robert Giannini, Videographer

* * * * *

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Age Group	Percentage
18-24	100
25-34	90
35-44	80
45-54	70
55-64	60
65-74	50
75-84	40
85-94	30
95-104	20

[illegible]

HIGHLY CONFIDENTIAL

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[illegible]

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[illegible]

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[REDACTED]

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Age Group	Percentage
18-24	10%
25-34	15%
35-44	20%
45-54	25%
55-64	30%
65-74	35%
75-84	40%
85+	45%

[illegible]

HIGHLY CONFIDENTIAL

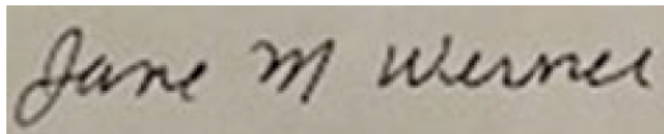
1 COMMONWEALTH OF MASSACHUSETTS)

2 SUFFOLK, SS.)

3 I, Jane M. Werner, RMR and Notary Public in and
4 for the Commonwealth of Massachusetts, do hereby
5 certify that there came before me on the 17th day of
6 May, 2024, at 9:38 a.m., the person hereinbefore
7 named, who was by me duly sworn to testify to the
8 truth and nothing but the truth of her knowledge
9 touching and concerning the matters in controversy
10 in this cause; that she was thereupon examined upon
11 her oath, and her examination reduced to typewriting
12 under my direction; and that the deposition is a
13 true record of the testimony given by the witness.

14 I further certify that I am neither attorney or
15 counsel for, nor related to or employed by, any
16 attorney or counsel employed by the parties hereto
17 or financially interested in the action.

18 In witness whereof, I have hereunto set my hand
19 and affixed my notarial seal this 22nd day of May,
20 2024.

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Notary Public

24 Commission expires 1/27/2028

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